K010748

JUL 1 0 2001

Summary of Safety & Effectiveness
Beckman SYNCHRON® Systems Hemoglobin A1c Reagent

1.0 Submitted By:

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2.0 Date Submitted:

13 March 2001

3.0 Device Name(s):

3.1 Proprietary Names

SYNCHRON® Systems Hemoglobin A1c (HbA1c) Reagent

3.2 Classification Name

Glycosylated hemoglobin assay (21 CFR § 864.7470)

4.0 Predicate Device(s):

BECKMAN Reagent	Predicate	Predicate Company	Docket Number
SYNCHRON Systems Hemoglobin A1c	Tosoh A1c 2.2 Plus Glycohemoglobin Assay	Tosoh Medics, Inc.	K972265

5.0 Description:

The SYNCHRON Hemoglobin A1c (HbA1c) Reagent kit contains two reagents, Hb and A1c for determining the Hemoglobin A1c concentrations in whole blood on SYNCHRON Clinical Systems.

6.0 Intended Use:

The SYNCHRON Hemoglobin A1c (HbA1c) Reagent kit, in conjunction with the SYNCHRON Hemoglobin A1c Calibrators and SYNCHRON HbA1c Hemolyzing Reagent, utilizes both colorimetric and immunoinhibition methods and is intended for the quantitative determination of hemoglobin A1c concentration as a percentage of total hemoglobin in whole blood on SYNCHRON Systems. The HbA1c assay is used to monitor long term blood glucose control in individuals with diabetes mellitus.

7.0 Comparison to Predicate(s):

The following tables show similarities and differences between the predicate identified in Section 4.0 of this summary.

Reagent	Aspect/Characteristic	Comments
SIMILARITIES		
SYNCHRON Systems HbA1c Reagent	Intended use	Same as the predicate
DIFFERENCES		
SYNCHRON Systems HbA1c Reagent	Methodology	SYNCHRON systems employ immunology and spectrophotometry; the Tosoh system uses high-pressure liquid chromatography (HPLC).
	Chemical Reaction	The SYNCHRON HbA1c assay uses two reagent cartridges to quantitate total hemoglobin (Hb) and A1c separately via colorimetric and immunoinhibition reactions. The Tosoh assay uses ion exchange reactions to separate hemoglobin fractions based on their molecular affinities.
	Formulation	Reagent formulations are specific to the methodology.
	Calibration	The SYNCHRON Hb andA1c assays have separate calibration schemes and math models; the Tosoh system uses a single calibration scheme.
	Sample Preparation	The SYNCHRON assay requires preparation of the whole blood sample with Hemolyzing Reagent; the Tosoh method is carried out without off-line sample pretreatment.

8.0 **Summary of Performance Data:**

The data in the Premarket Notification on safety and effectiveness supports a finding of substantial equivalence to chemistry test systems already in commercial distribution. Equivalence is demonstrated through method comparison and imprecision experiments that relate results obtained from the SYNCHRON HbA1c Reagent to the Tosoh Glycohemoglobin assay.

Method Comparison Study Results*

Analyte	N	Slope	Intercept	r	Predicate Method
SYNCHRON HbA1c Reagent	82	0.958	0.24%	0.990	Tosoh A1c 2.2 Plus Glycohemoglobin Assay

*EDTA patient specimens were analyzed in the range of 4.5% to 15.5% HbA1c. Data shown was collected using SYNCHRON CX Systems. Equivalency between SYNCHRON LX has been established by correlation analysis to SYNCHRON CX Systems.

Estimated SYNCHRON LX HbA1c Reagent Imprecision

Sample	Mean (%HbA1c)	S.D. (%)	%C.V.	N
Within-Run Imprecision				
Level 1	6.71	0.25	3.68	80
Level 2	8.25	0.27	3.29	80
Level 3	11.36	0.44	3.91	80
Total Imprecision				
Level 1	6.71	0.35	5.18	80
Level 2	8.25	0.53	6.48	80
Level 3	11.36	0.68	6.00	80

The Summary of Safety and Effectiveness information for the SYNCHRON Systems HbA1c Reagents are found in TAB 1 of this notice and are being submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and implementing regulation 21 CFR 807.92.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Mary Beth Tang
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Re: K010748
Trade Name: SYNCHRON® Systems Hemoglobin A1c (HbA1c) Reagent
Regulation Number: 21 CFR § 864.7470
Regulatory Class: II
Product Code: LCP
Dated: May 11, 2001
Received: May 14, 2001

Dear Ms. Tang:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): ~~Not yet assigned~~ K010748

Device Name: **SYNCHRON® Systems Hemoglobin A1c Reagent**

Indications for Use:

The SYNCHRON Systems Hemoglobin A1c (HbA1c) Reagent Kit, in conjunction with SYNCHRON HbA1c Calibrators and SYNCHRON HbA1c Hemolyzing Reagent, is intended for the quantitative determination of Hemoglobin A1c concentrations in whole blood on SYNCHRON Clinical Systems.

21 CFR 864.7470 Glycosylated hemoglobin assay

(a) *Identification.* A glycosylated hemoglobin assay is a device used to measure the glycosylated hemoglobins (A1a, A1b, A1c) in a patient's blood by a column chromatographic procedure. Measurement of glycosylated hemoglobin is used to assess the level of control of a patient's diabetes and to determine the proper insulin dosage for a patient. Elevated levels of glycosylated hemoglobin indicate uncontrolled diabetes in a patient.

(b) *Classification.* Class II.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K010748

Prescription Use ✓ OR Over-the-Counter Use _____
(per 21 CFR 801.109)